AO 120 (Rev. 2/99)

TO: **Mail Stop 8** **Director of the U.S. Patent & Trademark Office** **P.O. Box 1450** **Alexandria, VA 22313-1450**	**REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK**

In Compliance with 35 § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court Northern District of California on the following X Patents or ☐ Trademarks:

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
CV 11-03891 LB	August 9, 2011	Northern District of California, 1301 Clay St., RM 400S, Oakland, CA 94612
PLAINTIFF		DEFENDANT
SPINAL KINETICS, INC.		SYNTHES USA, LLC.

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	7,429,270		SEE ATTACHED
2			
3			
4			
5			

In the above—entitled case, the following patent(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		SEE ATTACHED
2		
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In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE
Richard W. Wieking		

Copy 1—Upon initiation of action, mail this copy to Commissioner Copy 3—Upon termination of action, mail this copy to Commissioner
Copy 2—Upon filing document adding patent(s), mail this copy to Commissioner Copy 4—Case file copy

c. Since plasma coating of the endplates, referred to in the Thesis Report, are designed for "perfect osteointegration," it is the best surface treatment for the "bone contacting plates" of claims 29-30.

d. Although the inventors disclosed in the patent specification that the claimed "bone contacting plates" are "made of titanium or titanium alloy," the inventors failed to disclose their preferred surface treatment. The Thesis Report identified an "optimal" surface treatment for "perfect osteointegration." Thesis Report, at §10.5.3.2. This "optimal solution" requires plasma spray coating the titanium surface. *Id.* This best and "optimal solution" that inventors Burri and Baumgartner contemplated was not disclosed in the patent specification.

e. The '270 patent is invalid and void under the provision of 35 U.S.C. § 112(2) because the claims are indefinite for at least one or more of the following reasons:

f. Nothing in the '270 Patent disclosure or within the knowledge of persons skilled in the art that allows for a clear objective standard to determine the scope and boundary for the claim term "substantially cylindrical" core.

g. A person skilled in the art would not be able to determine what shape of the core would have to deviate from a pure cylinder to no longer be "substantially cylindrical."

h. Also, nothing in the intrinsic record provides a clear objective standard to determine the scope of the claimed "substantially rigid" core or "rigid" core.

i. While the '270 patent describes the bone contacting plates are made from "titanium or a titanium alloy," there is no description of the dimensions of the bone contacting plates to determine their degree of rigidity or "substantial rigidity."

30. Hence, an actual, substantial and immediate controversy exists between Spinal Kinetics and Synthes as to whether the claims of the '270 Patent are valid.

31. Spinal Kinetics is therefore entitled to a declaration that the '270 Patent is invalid.

COUNT III

(Declaratory Judgment that the '270 Patent is not entitled to the filing date of the PCT Application)

32. Spinal Kinetics repeats and realleges each and every allegation contained in paragraphs 1-18 as if fully set forth herein.

33. Synthes is not entitled to the filing date of the PCT Application because it has not complied with the regulations of the United States Patent and Trademark Office ("the PTO") applicable to national stage filing under § 371, namely 37 C.F.R. § 1.78.

34. 37 C.F.R. § 1.78(a)(2)(i) and (ii) requires that the specification of the '270 Patent contain a reference to the PCT Application; but it does not.

35. It is plain that the specification of the '270 Patent does not contain any reference, typically found in the first few sentences in a patent, to the PCT Application.

36. An actual, substantial and immediate controversy exists between Spinal Kinetics and Synthes as to whether the claims of the '270 Patent are entitled to the filing date of the PCT Application.

37. Spinal Kinetics is therefore entitled to a declaration that the '270 Patent is not entitled to the filing date of the PCT Application.

PRAYER FOR RELIEF

WHEREFORE, Spinal Kinetics respectfully requests that this Court:

A. Declare that the '270 Patent is not entitled to the filing date of the PCT Application;

B. Declare that the '270 Patent, and each and every claim thereof, is invalid and void;

C. Declare that Spinal Kinetics intervertebral implants with the tantalum-containing sheath does not infringe any claim of the '270 Patent either literally or under the doctrine of equivalents;

D. Enjoin Synthes, its agents, servants, employees, and/or attorneys from asserting or continuing infringement litigation, from otherwise participating or assisting in infringement

litigation, and from threatening Spinal Kinetics or any of its customers, distributors, agents, or employees with infringement litigation, or charging any of them either verbally or in writing with infringement of the '270 Patent based on Spinal Kinetics' intervertebral implants with the tantalum-containing sheath;

E. Declare this to be an "exceptional" case within the meaning of 35 U.S.C. § 285, entitling Spinal Kinetics to an award of its reasonable attorneys' fees, expenses, and costs in this action; and

F. Grant such other further and different relief as the Court deems just and proper.

Dated: August 9, 2011

Respectfully submitted,

DICKSTEIN SHAPIRO LLP

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Clerk, U.S. District Court
Northern District of California
San Jose

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

CV11-03891 LB

SPINAL KINETICS, INC.,

Plaintiff,

v.

SYNTHES USA, LLC (f/k/a SYNTHES (U.S.A.)),

Defendant.

COMPLAINT FOR DECLARATORY JUDGMENT

JURY TRIAL DEMANDED

FAXED

FAXED

COMPLAINT

Plaintiff Spinal Kinetics, Inc. ("Spinal Kinetics"), by and through its attorneys, files the following Complaint for Declaratory Relief against Synthes USA, LLC (f/k/a Synthes (U.S.A.)) ("Synthes"), and hereby makes a jury demand and alleges as set forth below:

NATURE OF ACTION

1. This action is for a declaratory judgment of invalidity and non-infringement of U.S. Patent No. 7,429,270 ("the '270 Patent") entitled ""Intervertebral Implant." (A copy of the '270 Patent is attached hereto as Exhibit A).

THE PARTIES

2. Spinal Kinetics is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 595 N. Pastoria Avenue, Sunnyvale, California 94089.

3. Synthes is a Delaware limited liability company with its principal place of business at 1302 Wrights Lane East, West Chester, Pennsylvania 19380 in Chester County.

JURISDICTION AND VENUE

4. This action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102 and 103. Based on the allegations set forth in this Complaint, there is an actual controversy between Spinal Kinetics and Synthes with respect to the validity and infringement of the '270 Patent.

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

6. Synthes is subject to the personal jurisdiction of this Court because Synthes is a plaintiff and has been actively involved in litigation in this Court (Case No. 5:09-CV-01201 RMW) and has designated its attorneys as Sidley Austin LLP in Los Angeles as agents for service of process.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c).

BACKGROUND

8. Spinal Kinetics manufactures and sells intervertebral implants, including, but not limited to, the M6 intervertebral implant.

9. Upon information and belief, Synthes is the named assignee of the '270 Patent.

10. On or about November 12, 2008, Synthes filed a complaint in the District of Delaware against Spinal Kinetics, alleging that Spinal Kinetics' M6 implant infringes the '270 Patent.

11. The District of Delaware court issued an order to transfer the case to the Northern District of California on February 24, 2009.

12. On or about March, 19, 2009, the case was transferred to the Northern District of California (San Jose Division) as Case No. 5:09-CV-01201 RMW.

13. The court for the Northern District of California held a claim construction hearing on March 17, 2010 and issued a claim construction order on June 23, 2010.

14. The Northern District of California court construed "an elastic sheathing body" in independent claim 29 as "a homogeneous elastic sheathing body." (A copy of the Claim Construction Order is attached hereto as Exhibit B). Included in that ruling was a specific finding which made it clear that a non-homogenous sheath would be non-infringing.

15. In the wake of that claim construction, Spinal Kinetics immediately began designing and testing of an intervertebral disc having a tantalum-containing sheath that is non-homogenous, to increase the visibility of the sheath after the disc is implanted and to create an additional basis for non-infringement of claims 29-31 of the '270 Patent.

16. Spinal Kinetics completed its tantalum sheath redesign on May 3, 2011.

17. Under these circumstances, Spinal Kinetics has an objectively reasonable apprehension and belief that Synthes will institute and maintain litigation for alleged infringement of the '270 Patent based on Spinal Kinetics' intervertebral implants with the alternative tantalum-containing sheath redesign.

18. Hence, there is substantial and continuing justiciable controversy between Spinal Kinetics and Synthes as to whether the '270 Patent is valid and whether Spinal Kinetics'

intervertebral implants with the tantalum-containing sheath infringes or will infringe any claim of the '270 Patent.

COUNT I

(Declaratory Judgment of Non-Infringement of the '270 Patent)

19. Spinal Kinetics repeats and realleges each and every allegation contained in paragraphs 1-18 as if fully set forth herein.

20. Spinal Kinetics' intervertebral implants with the non-homogenous tantalum-containing sheath do not infringe any claim of the '270 Patent.

21. An actual, substantial and immediate controversy exists between Spinal Kinetics and Synthes as to whether the use, making, sale or offering for sale of Spinal Kinetics' intervertebral implants with the tantalum-containing sheath infringes any claim of the '270 Patent.

22. Spinal Kinetics is therefore entitled to a declaration that its intervertebral implants with the alternative tantalum-containing sheath redesign does not infringe, directly or indirectly by inducement or contribution, any claim of the '270 Patent.

COUNT II

(Declaratory Judgment of Invalidity of the '270 Patent)

23. Spinal Kinetics repeats and realleges each and every allegation contained in paragraphs 1-18 as if fully set forth herein.

24. The '270 Patent is invalid for failure to satisfy one or more of the conditions of patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103 and 112.

25. The '270 patent is invalid and void under the provision of 35 U.S.C. § 101 for at least one or more of the following reasons:

a. The purported invention described and claimed in the '270 Patent has no substantial, significant and practical utility. It was the subject of an incomplete masters research project by inventors Burri and Baumgartner that was described in their Thesis Report. (A copy of the Thesis Report is attached hereto as Exhibit C).

b. Recognizing that their masters project was incomplete, the inventors emphasized that these "concepts" described in the Thesis Report "are a good basis for further development" and estimated that the fiber-strengthened silicone concept, to which the '270 Patent is directed, would take substantially more than two years to develop because of the required dynamic mechanical testing and clinical trials. *Id.* at § 11, pg. 74.

c. According to inventors Burri and Baumgartner, "little knowledge is available on the use of fibers and silicone and, in particular, their combination." *Id.* at §10.7, p. 73.

d. The inventors of the '270 patent failed to perform mechanical fatigue testing or clinical testing of their purported invention prior to the filing date of their patent application.

e. The patent application of the '270 Patent was filed with no basis for believing that its subject matter had any substantial, significant and practical utility, but rather with a recognition that no such basis existed.

26. The '270 patent is invalid and void under the provision of 35 U.S.C. § 102 for at least one or more of the following reasons:

a. For example, U.S. Patent No. 3,867,728, entitled "Prosthesis For Spinal Repair" to Stubstad et al. issued February 25, 1975 (hereinafter the "Stubstad '728 patent") is anticipatory prior art pursuant to 35 U.S.C. Section 102(b). (A copy of the Stubstad '728 patent is attached hereto as Exhibit D).

b. The Stubstad '728 patent describes: an intervertebral implant (element 10) for implantation between an upper and lower vertebrae, the implant having a central axis, the implant comprising; a first substantially rigid bone contracting plate (element 19) , a second substantially rigid bone contacting plate (element 19'), a third plate (element 18) operatively coupled to the first bone contacting plate, the third plate including a plurality of openings (col. 8, line 1 the plate is "perforate"), a fourth plate (element 18') operatively coupled to the second bone contacting plate, the fourth plate including a plurality of openings (col. 8, lines 22, 23); a central part (element 15) substantially located between the third and fourth plates, the central part including a flexible core (element 16) and a fiber system (element 29), wherein the core includes a top surface (element 27) and a bottom surface (element 30), the top surface of the core being in

contact with the third plate and the bottom surface of the core being in contact with the fourth plate, and wherein the fiber system (element 29) at least partially surrounds the core, and is at least partially received within the plurality of openings formed in the third and fourth plates (col. 8, lines 1-42) so that the fiber system is joined to the third and fourth plates; and an elastic sheathing body (element 13) at least partially surrounding the fiber system and the core, and connected to the third and fourth plates. The plates are described as being of metal.

c. Thus, the Stubstad '728 patent meets each and every element of the claimed invention of the '270 Patent, and therefore, renders the claims of the '270 patent invalid and void pursuant to 35 U.S.C. Section 102(b).

d. The '270 Patent is also anticipated by inventors' Burri and Baumgartner's Thesis Report and public disclosures thereof.

e. The Thesis Report discloses each and every element of the claimed invention of the '270 Patent. *See* Exhibit C, pgs. 71 and 72.

f. The Thesis Report and public disclosures thereof constitutes anticipatory prior art, and therefore, renders the claims of the '270 patent invalid and void pursuant to 35 U.S.C. Section 102(b).

27. The '270 patent is invalid and void under the provision of 35 U.S.C. § 103 for at least one or more of the following reasons:

a. For example, the Stubstad '728 patent in view of a publication entitled "Development and Characterization of a Prosthetic Intervertebral Disc" dated November 1998, Robert Garryl Hudgins, Georgia Institute of Technology (hereinafter the "Hudgins Thesis"), renders the claims of the '270 Patent obvious under 35 U.S.C. §103. (A copy of the Hudgins Thesis is attached hereto as Exhibit E).

b. Both the Stubstad '278 patent and the Hudgins Thesis involve the design of intervertebral implants to accomplish effective mating with intervertebral surfaces and include a core system. A person of ordinary skill in the art would have combined these references.

c. When so combined, these references illustrate: (1) an intervertebral implant for implantation between an upper and lower vertebrae, the implant having a central axis, the implant

comprising: (2) a first substantially rigid bone contacting plate having an external surface extending generally transversely to the central axis for contacting at least a portion of the upper vertebra; (3) a second substantially rigid bone contacting plate having an external surface extending generally transversely to the central axis for contacting at least a portion of the lower vertebra; (4) a third plate operatively coupled to the first bone contacting plate, the third plate including a plurality of openings; (5) a fourth plate operatively coupled to the second bone contacting plate, the fourth plate including a plurality of openings; (6) a central part substantially located between the third and fourth plates, the central part including a flexible core and a fiber system; (7) wherein the core is substantially cylindrical and includes a top surface and a bottom surface, the top surface of the core being in contact with the third plate and the bottom surface of the core being in contact with the fourth plate, and (8) wherein the fiber system at least partially surrounds the core, and is at least partially received within the plurality of openings formed in the third and fourth plates so that the fiber system is joined to the third and fourth plates; and (9) an elastic sheathing body at least partially surrounding the fiber system and the core, and connected to the third and fourth plates.

d. Hence, it would have been obvious to add the elastic sheathing body disclosed in the Stubstad '278 patent to enclose the central part of the intervertebral implant disclosed by the Hudgins Thesis, thus making the claims of the '270 Patent obvious to one of ordinary skill in the art and therefore invalid.

28. The '270 patent is invalid and void under the provision of 35 U.S.C. § 112(1) for failure to comply with the written description and enablement requirements for at least one or more of the following reasons:

a. Upon information and belief, the '270 Patent issued on September 30, 2008 based upon an application that entered the national stage pursuant to 35 U.S.C. Section 371 on July 25, 2006, claiming priority to a PCT Application filed on April 14, 2003. (A copy of the PCT Application is attached hereto as Exhibit F).

b. The disclosure of the PCT Application and the '270 Patent failed to:

i. describe and enable "substantially rigid" bone contacting plates,

ii. describe and enable the plurality of "openings" in the third and fourth plates,

iii. describe the "flexible core," and

iv. describe the "substantially cylindrical" core.

c. These terms were never used in the specification or in the originally filed claims of the PCT Application and the '270 Patent, but were introduced by amendment during the prosecution of the U.S. application in a February 19, 2008 response to an office action ("2008 Response"). (A copy of the 2008 Response is attached hereto as Exhibit G).

d. Hence, these terms are new matter unsupported by the written description of the PCT Application and the '270 Patent. Moreover, a person of ordinary skill in the art would require undue experimentation to (1) form openings on the cover plates, and (2) determine the appropriate "rigidity" of the bone contacting plates.

29. The '270 patent is invalid and void under the provision of 35 U.S.C. § 112(1) for failure to comply with the best mode requirement for at least one or more of the following reasons:

a. The Thesis Report analyzes multiple intervertebral implant solutions. *See* Exhibit C at §10.2, pg. 61. "The solution with the largest number of points is the *best,* that with the lowest the worst." *Id.* (emphasis added). Inventors Burri and Baumgartner identified solutions 1, 2 and 3 as the best and further described each in their Thesis Report. *Id.* at §10.3, pg. 62.

b. In connection with solutions 2 and 3, the inventors emphasized that the "[l]ong-term growth, and thus permanent attachment to the endplate structure of the vertebrae is guaranteed by a *coated titanium surface." Id.* at §10.5.3.2, pg. 69 (emphasis added). "In a similar way to *ProDisc,* the proven 'plasma spray coating' is the *optimal solution* for perfect osteointegration." *Id.* (emphasis added). Table 4.1 of the Thesis Report further describes ProDisc having endplates of titanium with plasma spray coating. *See id.* at §4.1, pg. 19. Moreover, Table 10.4 of their third solution proposes "titanium with bioactive coating" for the endplates. *See id.* at §10.6.5, pg. 72.